ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 015581 0611 Rev. 00

Manufacturer:

Respironics, Inc.
1001 Murry Ridge Lane
Murrysville PA 15668
USA

Product Category(ies):

Continuous Ventilators, Non-Continuous Ventilators, Positive Airway Pressure Units (Bi-level Continuous), Masks, Breathing Circuits, Humidifiers, Ventilatory Effort Recorders, Electroencephalograph, Sleep Therapy Diagnostic Devices, Controllers for Sleep Therapy and Ventilator Devices, Oxygen Therapy, Physiological Monitoring Equipment, Mechanical Positive Pressure Airway Secretion-Clearing Devices, Nasal Cannulae, and Sleep Position Training Devices for the Treatment of Positional Sleep Apnea. Non-active medical devices for respiratory care (Respiratory muscle trainers, nebulizers, mouthpieces, facemasks, tubing, connectors and T pieces) and active medical devices for respiratory care (nebulizers and ventilators)

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II.
This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 015581 0611 Rev. 00

Report No.: 72161399

Valid from: 2021-03-15
Valid until: 2024-05-26

Date, 2021-03-15

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 015581 0611 Rev. 00

./.

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®